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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/585,019

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Helle Wittorff

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EXAMINER

GWARTNEY, ELIZABETH A

ART UNIT

PAPER NUMBER

1794

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/585,019	Applicant(s) WITTORFF, HELLE	
	Examiner Elizabeth Gwartney	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20090928</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Amendment filed 28 September 2009 has been entered. Claim 7 has been cancelled. Claims 1-6 and 8-32 are pending in this application.
2. The previous 112 2nd Paragraph rejections with regards to claims 7, 14, 16-17, 19, 30 and 32 have been withdrawn in light of Applicant's amendments made 28 September 2009.
3. The 35 U.S.C. 103(a) rejection of claims 1-2, 4-5, 7-29 and 31-32 as unpatentable over Thorengaard et al. (WO 2004/004480) in view of Wittorff et al. (WO 02/076230) is withdrawn as a result of Applicant's submission under 35 U.S.C 103 (c).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 2, the recitation "solely at least one biodegradable polymer" renders the claim indefinite because it is unclear if the gum base contains one (i.e. solely) or more biodegradable polymers. The terms "solely" and "at least one" appear to conflict. Further, it is unclear what quantity of "at least one biodegradable polymer" is encompassed by the phrase "substantially solely."

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-3, 5-6, 8-18 and 20-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bunczek et al. (US 6,017,566) in view of Gmunder et al. (US 6,200,608).

Regarding claim 1-3, 5-6, 8 and 24-25, Bunczek et al. disclose a gum base comprising approximately 1 to about 80% by weight biodegradable polymer, i.e. polyester, produced through reaction of at least one alcohol and at least one acid including carboxylic acids (C1/L53-62, C2/L45-46, C3/L23, C4/L42-43)) and about 20 to about 60% by weight synthetic elastomer (i.e. non-biodegradable polymer - C10/L45-48).

Bunczek et al. do not disclose gum base granules or that the gum base has a water content of less than 1.0% by weight.

Gmunder et al. teach a particulated chewing gum base (Abstract, C2/L12-18). Gmunder et al. teach that there are reduced processing, preparation and packaging costs associated with making a particulated chewing gum base compared to the conventional method (C13/L4-10). Gmunder et al. teach that a particulated gum base can be easily metered by automatic feeders

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(C13/L10-12). Further, Gmunder et al. teach that the gum base ingredients are particles 0.6 mm or less (C6/L13-18) and the gum base is free of liquid ingredients (C2/L36-37).

Bunczek et al. and Gmunder et al. are combinable because they are concerned with the same field of endeavor, namely, gum base compositions. It would have been obvious to one of ordinary skill in the art at the time of the invention to have particulated (i.e. granulated), the chewing gum base of Bunczek et al., as taught by Gmunder et al., for the purpose of reducing processing, preparation and packaging costs and allowing the use of automatic feeders .

Given that Gmunder teach particulating a gum base that is free of liquid ingredients, it is clear that the gum base would intrinsically have a moisture content of less than 1%.

Regarding claims 9-10, modified Bunczek et al. disclose all of the claim limitations as set forth above. Given that Bunczek et al. does not disclose at least one high molecular weight elastomeric biodegradable polymer, it is clear that the amount of high molecular weight elastomeric biodegradable polymer in the gum base would intrinsically be 0%. Further, given Bunczek et al. disclose 0% of a high molecular weight elastomeric biodegradable polymer, it is clear that the limitations of claim 10 are met.

Regarding claims 11-12, modified Bunczek et al. disclose all of the claim limitations as set forth above. Bunczek et al. also disclose that the gum base comprises about 20 to about 60 wt % of a synthetic elastomer including polyvinyl acetate having a weight average molecular weight of about 2,000 to 90,000 g (C10/L45-60).

Regarding claim 13, modified Bunczek et al. disclose all of the claim limitations as set forth above. Given Bunczek et al. does not disclose that the gum base comprises sweetener, it is clear that the gum base comprises sweetener in an amount of less than 50% by weight.

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Regarding claim 14, modified Bunczek et al. disclose all of the claim limitations as set forth above. Given Bunczek et al. do not disclose a gum base comprising lubricants, anti-adherents and glidants the limitation of claim 14 is met (see C10/L45-61, C9/Base Examples 8-13).

Regarding claim 15, modified Bunczek et al. disclose all of the claim limitations as set forth above. Bunczek et al. also discloses that the gum base comprises natural rosin ester, i.e. natural resins (C11/L16-17). Given Bunczek et al. disclose a gum base comprising natural resins, it is clear that the natural resins would intrinsically provide an improved and sticky texture of the gum base when applied in chewing gum formulations.

Regarding claims 16-18, modified Bunczek et al. disclose all of the claim limitations as set forth above. Bunczek et al. also disclose that the gum does not include wax (C11/43-45), or fat (C7/Base Example 1-4, C9/Base Example 8-11) and comprises about 4 to about 35 wt% filler (C10/L45-53).

Regarding claim 20, modified Bunczek et al. disclose all of the claim limitations as set forth above. Bunczek et al. also discloses that the gum base comprises about 5 to about 55% by weight elastomer plasticizer, i.e. synthetic resin, including terpene resins (C10/L49-50, C11/L23-25).

Regarding claim 21, modified Bunczek et al. disclose all of the claim limitations as set forth above. Bunczek et al. also disclose that the gum base comprises from about 5 to about 35% by weight softener (i.e. tallow, hydrogenated tallow hydrogenated and partially hydrogenated vegetable oil, cocoa butter - C10/L50-51, C11/L33-36).

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Regarding claim 22, modified Bunczek et al. disclose all of the claim limitations as set forth above. While Bunczek et al. disclose that the gum base may comprise wax (C11/L42-45), the reference does not disclose that it is in an amount of about 2% to about 30% by weight of the gum base. As chewiness is a variable that can be modified, among others, by adjusting the amount of wax in the gum base, the precise amount of wax would have been considered a result effective variable by one of ordinary skill in the art at the time of the invention. As such, without showing unexpected results, the claimed amount of wax cannot be considered critical.

Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine techniques, the amount of wax in the gum base granules of modified Bunczek et al. to obtain the desired chewiness in the resulting chewing gum product (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

Regarding claim 23, modified Bunczek et al. disclose all of the claim limitations as set forth above. Bunczek et al. also discloses mixing flavoring agents into the gum base prior to forming into a chewing gum (C7/Gum Examples 5-7, C9-10/Gum Examples 14-18).

Regarding claim 26, modified Bunczek et al. disclose all of the claim limitations as set forth above. Bunczek et al. also disclose rolled, extruded or casted (i.e. compressed) chewing gum comprising gum base (C12/L55-65).

Regarding claim 27, modified Bunczek et al. disclose all of the claim limitations as set forth above. Bunczek et al. also disclose a gum base comprising about 20 to about 60% by

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weight synthetic elastomer (i.e. non-biodegradable polymer - C10/L45-48) wherein the chewing gum comprises gum base.

Regarding claim 28, modified Bunczek et al. disclose all of the claim limitations as set forth above. Bunczek et al. also disclose that the gum base is mixed and formed together with ingredients including sweeteners, flavorings, fillers, and emulsifiers (C11/L46-52, C12/L55-61).

Regarding claims 29-30, modified Bunczek et al. disclose all of the claim limitations as set forth above. Given that Gmunder teach particulating a gum base that is free of liquid ingredients (C2/L36-37), it is clear that the gum base would intrinsically have a moisture content of less than 1% or 0%.

Regarding claim 31, modified Bunczek et al. disclose all of the claim limitations as set forth above. Bunczek et al. also disclose that the gum base comprises two biodegradable polymers (C9/Base Examples 8).

Regarding claim 32, modified Bunczek et al. disclose all of the claim limitations as set forth above. While modified Bunczek et al. disclose biodegradable gum base granules in a formed chewing gum, the references do not disclose wherein said biodegradable gum base granules are used together with conventional non-biodegradable gum base granules.

Given Gmunder et al. teach non-biodegradable gum base granules, since modified Bunczek et al. disclose biodegradable gum base granules, it would have been obvious to one of ordinary skill in the art at the time of the invention to have combined both types of granules to make a chewing gum with a desired level of degradability.

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9. Claims 1, 4 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wittorff et al. (WO 02/076230) in view of Gmunder et al. (US 6,200,608).

Regarding claims 1 and 4, Wittorff et al. disclose a gum base comprising a biodegradable polyester polymer obtainable by the polymerization of cyclic ester monomers (Abstract, p.4/L13-15).

Wittorff et al. do not disclose gum base granules or that the gum base has a water content of less than 5.0% by weight.

Gmunder et al. teach a particulated chewing gum base (Abstract, C2/L12-18). Gmunder et al. teach that there are reduced processing, preparation and packaging costs associated with making a particulated chewing gum base compared to the conventional method (C13/L4-10). Gmunder et al. teach that a particulated gum base can be easily metered by automatic feeders (C13/L10-12). Further, Gmunder et al. teach that the gum base ingredients are particles 0.6 mm or less (C6/L13-18) and the gum base is free of liquid ingredients (C2/L36-37).

Wittorff et al. and Gmunder et al. are combinable because they are concerned with the same field of endeavor, namely, gum base compositions. It would have been obvious to one of ordinary skill in the art at the time of the invention to have particulated (i.e. granulated), the chewing gum base of Wittorff et al., as taught by Gmunder et al., for the purpose of reducing processing, preparation and packaging costs and allowing the use of automatic feeders .

Given that Gmunder teach particulating a gum base that is free of liquid ingredients (C2/L36-37), it is clear that the gum base would intrinsically have a moisture content of less than 5%.

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Regarding claim 19, modified Wittorff et al. disclose all of the claim limitations as set forth above. Wittorff et al. also disclose a composition of chewing gum base which is admixed with chewing gum additives including pharmaceutically or biologically active substances (p.16/L8-15, p.20/L9-10).

Response to Arguments

10. Applicant's arguments filed 28 September 2009 have been fully considered but they are not persuasive.

Applicant argues that while “the present invention and all documents cited disclose gum base compositions, prior to the present invention there was never been any connection between the field of compressed chewing gum and the field of biodegradable chewing gum.”

In response to applicant's argument that Bunczek et al., Wittorff et al. and Gmunder et al. are nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, these references are all in the field of applicant's endeavor, namely, chewing gum or more specifically, chewing gum base compositions.

It is the Examiner's position that one of ordinary skill in the art of chewing gum making a biodegradable gum base, as in Bunczek et al., would have looked to Gmunder et al. which teach particulating gum base for the purpose of reducing processing, preparation and packaging costs and allowing the use of automatic feeders.

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The fact that the use of biodegradable polymers in chewing gum is fairly "new" does not mean that the knowledge is excluded from the chewing gum art.

Applicant finds that a skilled person would refrain from using a degradable polymer in the invention of Gmunder et al. because it seems likely that degradable polymers may start to pre-degrade if kept as granules with large surface/volume ratio for a long time.

It is not clear how applicant's statement is relevant to the field of biodegradable polymers. If applicant's statement were true, the degradable polymers used in a chewing gum composition would pre-degrade if the chewing gum was kept for a long time, for example, in a package on the shelf in a store.

Applicant argues that the chewing gum base of Gmunder et al. is not free of liquid ingredients because the gum base comprises up to 47% softeners including glycerides and lecithin which typically inherently contain water/moisture. Further, applicants find that some softeners used in chewing gum "comprise perhaps 25% by weight of water."

While Gmunder et al. teach that the gum base may comprise up to 47% softeners, the reference also discloses that as little as 4% can be used. Further, while Gmunder et al. teach softeners including glycerides and lecithin, the reference also teaches the use of de-oiled lecithin (C7/L20-21). Therefore, for example, adding 4% de-oiled lecithin to a gum base composition, wherein de-oiled lecithin comprises less than 1% water, would contribute less than 1% water.

Further, it is noted, that at C2/L36-37, Gmunder et al. teach a gum base composition that is free of liquid ingredients.

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Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Gwartney whose telephone number is (571) 270-3874. The examiner can normally be reached on Monday - Friday; 7:30AM - 3:30PM EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. G./

Examiner, Art Unit 1794

/Keith D. Hendricks/

Supervisory Patent Examiner, Art Unit 1794